

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Karki et al.

Serial No. 10/506,710

Filed: September 7, 2004

For: Solid Forms of Salts with Tyrosine Kinase Activity



Art Unit: 1624

Examiner: To be Assigned

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97**

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

**MERCK & CO., INC.**

By Christine Dore Date 2/14/05

**INFORMATION DISCLOSURE STATEMENT**

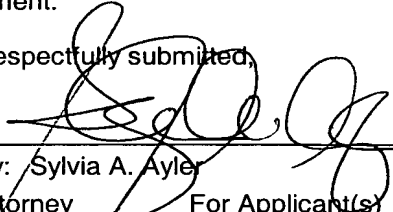
5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- the attached information is filed within three months of the filing date of the captioned case.
- the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

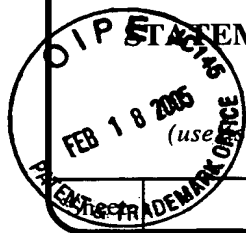
Respectfully submitted,  
  
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 (732)594-4909  
 Date: February 14, 2005

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE**

**STATEMENT BY APPLICANT**

(use many sheets as necessary)



**COMPLETE IF KNOWN**

Application Number	10/506,710
Filing Date	September 7, 2004
First Named Inventor	Karki et al.
Group Art Unit	1624
Examiner Name	To Be Assigned
Attorney Docket Number	21087

1 of 9

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
	A.	6,069,134		Roth et al.	05/30/2000
	B.	4,231,938		Monaghan et al.	11/04/1980
	C.	5,177,080		Angerbauer et al.	01/05/1993
	D.	4,294,926		Monaghan et al.	10/13/1981
	E.	4,319,039		Albers-Schonberg	03/09/1982
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	G.	4,820,850		Verhoeven et al.	04/11/1989
	H.	4,916,239		Treiber	04/10/1990
	I.	4,346,227		Terahara et al.	08/24/1982
	J.	4,537,859		Terahara et al.	08/27/1985
	K.	4,410,629		Terahara et al.	10/18/1983
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	R.	5,118,853		Lee et al.	06/02/1992
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	T.	5,356,896		Kabadi et al.	10/18/2001

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		Office	Number	Kind Code (if known)		
	U.	PCT	WO 01/29025	A2	Merck & Co. Inc.	04/26/2001
	V.	PCT	WO 96/30343	A1	Merck & Co. Inc.	10/03/1996
	X.	EP	0 618 221	A2	Bristol-Myers Squibb	03/29/2004
	Y.	EP	0 675 112	A1	Bristol-Myers Squibb	03/31/2005
	Z.	EP	0 604 181	A1	Eli Lilly and Company	12/20/1993
	AA.	EP	0 696 593	A2	Bristol-Myers Squibb	08/09/1995
	BB.	PCT	WO 94/19357	A1	Merrell Dow Pharmaceuticals Inc.	09/01/1994
	CC.	PCT	WO 95/08542	A1	Kyowa Hakko Kogyo Co., Ltd.	03/30/1995
	DD.	PCT	WO 95/11917	A1	Parke, Davis & Company	05/04/1995
	EE.	PCT	WO/10515	A1	Schering Corporation	04/20/1995

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Sheet	2	of	9	Attorney Docket Number	21087P	

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		Number	Kind Code (if known)		
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	GG.	5,273,995		Roth	12/28/1993
	HH.	4,681,893		Roth	07/21/1987
	II.	5,489,691		Butler et al.	02/06/1996
	JJ.	5,342,952		Bulter et al.	08/30/1994
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	LL.	5,523,430		Patel et al.	06/04/1996
	MM.	5,532,359		Marsters Jr. et al.	07/02/1996
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	TT.	5,661,152		Bolton et al.	08/26/1997
	UU.	5,532,359		Marsters Jr. et al.	07/02/1996

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		Office	Number	Kind Code (if known)		
	VV.	PCT	WO 95/12612	A1	Warner-Lambert Company	05/11/1995
	WW.	PCT	WO 95/12572	A1	ZF Friedrichshafen Ag	06/08/1995
	XX.	PCT	WO 95/10514	A1	Schering Corporation	04/20/1995
	YY.	PCT	WO 95/10516	A1	Schering Corporation	04/20/1995
	ZZ.	PCT	WO 95/34535	A1	Rhone Poulenc Rorer S.A.	12/21/1995
	1.	PCT	WO 95/25086	A1	Eisai Co, Ltd.	09/21/1995
	2.	PCT	WO 96/05529	A1	Micron Optics Inc.	02/22/1996
	3.	PCT	WO 96/06138	A1	SKW Trostberg Aktiengesellschaft	02/29/1996
	4.	PCT	WO 96/21456	A1	Univeristy of Pittsburgh	07/18/1996
	5.	PCT	WO 96/22278	A1	Rhone Poulenc Rorer S.A.	07/25/1996

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			Filing Date	September 7, 2004
			First Named Inventor	Karki et al.
			Group Art Unit	1624
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	5.	PCT	WO 96/24611	A1	Rhone Poulenc Rorer S.A.	08/15/1996
	6.	PCT	WO 96/24612	A1	Rhone Poulenc Rorer S. A.	08/15/1996
	7.	PCT	WO 96/05168	A1	Banyu Pharmaceutical	02/22/1996
	8.	PCT	WO 96/05169	A1	Banyu Pharmaceutical	02/22/1996
	9.	PCT	WO 96/00736	A1	Warner Lambert Company	01/11/1996
	10.	PCT	WO 96/17861	A1	Warner-Lambert Company	06/13/1996
	11.	PCT	WO 96/33159	A1	Abbott Laboratories	10/24/1996
	12.	PCT	WO 96/34850	A1	Abbott Laboratories	11/07/1996
	13.	PCT	WO 96/34851	A1	Abbott Laboratories	11/07/1996
	14.	PCT	WO 96/30017	A1	Schering Corporation	10/03/1996

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		Office	Number	Kind Code (if known)		
	15.	PCT	WO 97/03047	A1	Rhone Poulenc Rorer S.A.	01/30/1997
	16.	PCT	WO 96/30018	A1	Schering Corporation	10/03/1996
	17.	PCT	WO 96/30362	A1	Schering Corporation	10/03/1996
	18.	PCT	WO 96/30363	A1	Schering Corporation	10/03/1996
	19.	PCT	WO 96/31111	A1	Schering Corporation	10/10/1996
	20.	PCT	WO 96/31477	A1	Schering Corporation	10/10/1996
	21.	PCT	WO 96/31478	A1	Schering Corporation	10/10/1996
	22.	PCT	WO 96/31501	A1	Schering Corporation	10/10/1996
	23.	PCT	WO 97/00252	A1	Warner-Lambert Company	01/03/1997

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Application Number	10/506,710
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		Office	Number	Kind Code (if known)		
	24.	PCT	WO 97/03050	A1	Rhone Poulenc Rorer	01/30/1997
	25.	PCT	WO 97/04785	A1	Symphar S.A.	02/13/1997
	26.	PCT	WO 97/02920	A1	Datacon Schweitzer & Zeindl GMBH	01/30/1997
	27.	PCT	WO 97/17070	A1	University of Pittsburgh	05/15/1997
	28.	PCT	WO 97/23478	A1	Schering Corporation	07/03/1997
	29.	PCT	WO 97/26246	A1	Warner Lambert Company	07/24/1997
	30.	PCT	WO 97/30053	A1	Biomeasure Incorporated	08/21/1997
	31.	PCT	WO 97/44350	A1	Warner Lambert Company	11/27/1997
	32.	PCT	WO 98/02436	A1	Bristol Myers Squibb	01/22/1998
	33.	PCT	WO 95/32987	A1	Isis Pharmaceuticals Inc.	12/07/1995

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	34.	PCT	WO 95/12572	A1	Abbott Laboratories	05/11/1995
	35.	PCT	WO 97/18813	A1	Merck & Co. Inc.	05/29/1997
	36.	PCT	WO 97/21701	A1	Janssen Pharmaceutica N.V.	06/19/1997
	37.	PCT	WO 97/23478	A1	Schering Corporation	07/03/1997
	38.	PCT	WO 97/38665	A2	Merck & Co. Inc.	10/25/1997
	39.	PCT	WO 98/28980	A1	Merck & Co. Inc.	07/09/1998
	40.	PCT	WO 98/29119	A1	Merck & Co. Inc.	07/09/1998
	41.	PCT	WO 84/02131	A1	Sandoz Ag	06/07/2004

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Sheet	7	of	9	Attorney Docket Number	21087

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	42.	T. Hasegawa et al., "Intracortical Osteoblastic Osteosarcoma with Oncogenic Rickets", 1999, pp. 41-45, Vol. 28, International Skeletal Society.
	43.	M. P. Seed et al., "The Inhibition of Colon-26 Adenocarcinoma Development and Angiogenesis by Topical Diclofenac in 2.5% Hyaluronan", 1997, pp. 1625-1629, Vol. 57, Cancer Research.
	44.	M. A. Gimbrone, Jr. et al., "Tumor Growth and Neovascularization: An Experimental Model Using the Rabbit Cornea", pp. 413-419, Vol. 52, No. 2, J. of the National Cancer Institute.
	45.	B. Endrich et al., "Microcirculatory Blood Flow, Capillary Morphology, and Local Oxygen Pressure of the Hamster Amelanotic Melanoma A-Mel-3", 1982, pp. 475-482, Vol. 69, No. 3, JNCI.
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	48.	M. Dhanbal et al., "Endostatin: Yeast Production, Mutants, and Antitumor Effect in Renal Cell Carcinoma", 1999, pp. 189-197, Vol. 59, Cancer Research.
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	50.	M. Shibuya et al., "Nucleotide Sequence and Expression of a Novel Human Receptor-Type Tyrosine Kinase Gene ( <i>flt</i> ) Closely Related to the <i>fms</i> Family", 1990, pp. 519-524, Vol. 5, Oncogene.
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	53.	K. J. Kim et al., "Inhibition of Vascular Endothelial Growth Factor-Induced Angiogenesis Suppresses Tumour Growth in Vivo", 1993, pp. 841-844, Vol. 362, Letters of Nature.
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Examiner Signature	Date Considered
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Sheet	8	of	9	Attorney Docket Number	21087

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Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
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	58.	M. Majima et al., "Significant Roles of Inducible Cyclooxygenase (COX)-2 in Angiogenesis in Rat Sponge Implants", 1997, pp. 105-114, Vol. 75, Jpn. J. Pharmacol.
	59.	A. Amirkhosravi et al., "Blockade of GpIIb/IIIa Inhibits the Release of Vascular Endothelial Growth Factor (VEGF) from Tumor Cell -Activated Platelets and Experimental Metastasis", 1999, pp. 285-292, Vol. 10, Platelets.
	60.	S. Harada et al., "Expression and Regulation of Vascular Endothelial Growth Factor in Osteoblasts", 1995, pp. 76-80, Vol. 313, C. Orthopedics and Related Research.
	61.	J. Rak et al., "Mutant ras Oncogenes Upregulate VEGF/VPF Expression: Implications for Induction and Inhibition of Tumor Angiogenesis", 1995, pp. 4575-4580, Vol. 55, Cancer Research.
	62.	L. Diaz-Flores et al., "Intense Vascular Sprouting from Rat Femoral Vein Induced by Prostaglandins E1 and E2", 1994, pp. 68-76 Vol. 238, The Anatomical Record.
	63.	M. Yalpani, "Cholesterol-Lowering Drugs", 1996, pp. 85-89, Chemistry & Industry.
	64.	V. Chiarugi et al., "Cox-2, iNOS and p53 as Play-Makers of Tumor Angiogenesis (Review)", 1998, pp. 715-719, Vol. 2, International J. of Molecular Medicine.
	65.	D. H. Ausprunk et al., "Differentiation of Vascular Endothelium in the Chick Chorioallantois: A Structural and Autoradiographic Study", 1974, pp. 237-248, Vol. 38, Developmental Biology.
	66.	M. Tsujiji et al., "Cyclooxygenase Regulates Angiogenesis Induced by Colon Cancer Cells", 1998, pp. 705-716, Vol. 93, Cell.
	67.	X. Xin et al., "Peroxisome Proliferator-activated Receptor $\gamma$ Ligands are Potent Inhibitors of Angiogenesis in Vitro and in Vivo", pp. 9116-9121, Vol. 274, No. 13, J. of Biological Chemistry.
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Examiner Signature		Date Considered	
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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			Application Number	10/506,710	
			Filing Date	September 7, 2004	
			First Named Inventor	Karki et al.	
			Group Art Unit	1624	
			Examiner Name	To Be Assigned	
Sheet	9	of	9	Attorney Docket Number	21087

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	72.	M. M. L. Deckers et al., "Expression of Vascular Endothelial Growth Factors and Their Receptors During Osteoblast Differentiation", 2000, pp. 1667-1674, Vol. 141, No. 5, Endocrinology.
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